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| 09/755,204 | 01/04/2001 | Xiangzhong Yang | 883933.0053 | 4830 |

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EXAMINER
WOITACH, JOSEPH T

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1632 | |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/755,204

Applicant(s)

YANG ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-62 and 64-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-62, 64-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date August 14, 2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This application claims benefit to provisional applications 60/174,383, filed January 4, 2000 and 60/174,424, filed January 4, 2000.

Applicants amendment filed December 12, 2003, as been received and entered. Claims 48, 52-54, 56, 57, 59, 60, 64-68, 70-75 and 78-81 have been amended. Claims 48-62 and 64-81 are pending and currently under examination.

Information Disclosure Statement

The supplemental information disclosure filed August 14, 2003, has been received and entered. A signed copy of the PTO-1449 is provided with this action.

It is noted that the on the cover sheet that the title of the invention and the assigned art unit are incorrect. However, the references appear relevant to the instantly claimed invention and the remaining information, inventor and USSN is correct.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-62 and 64-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 30 and 31 of copending Application No. 10/274,432. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to methods of making a reconstituted embryo by nuclear transfer which can in turn can be developed into an intact animal. Further, each encompass using somatic cells as the donor cell and making genetic alterations to that cell to incorporate a stably integrated sequence to be expressed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 53, 54, 56, 57, 65, 67, 68, 71, 73, 74, 77, 79 and 80 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

The amendments to the claims to include only "non-human" animal, embryo, and fetus has addressed and obviated the basis of the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 52, 59-62, 64, 70 and 76 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nuclear transfer between donor cell and recipient oocytes of the same species, does not reasonably provide enablement for trans-species nuclear transfer is withdrawn.

Amendments to the claims to encompass methodology wherein the oocyte and donor nuclear material is from the same species has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 and 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to claim 52 to be dependent on claim 51 to support the antecedent basis of 'subpopulation' has obviated the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 49, 51, 52, 59-61 and 70 rejected under 35 U.S.C. 102(b) as being anticipated by Cibelli *et al.* is withdrawn.

Amendments to the claims to include the specific step of culturing the somatic cell donor for at least five passages” has differentiated the claimed invention from that taught by Cibelli *et al.*

Claims 53-58, 71-75 and 77-81 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cibelli *et al.*

Claims 65-69 stand rejected under 35 U.S.C. 102(b) as being anticipated by Plump *et al.*

For both rejections, Applicants point out the dependency of the claims and that the claims specifically encompass a product by process. Applicants note that none of the references teach the same methods to generate the claimed products, and argue that the Examiner has failed to fully consider each of the method steps in obtaining the claimed non-human animal. See Applicants amendment, pages 11-13. Applicants arguments have been fully considered, but not found persuasive.

Applicants acknowledge that the references teach a non-human animal, tissue, organ and cell, however they fail to point out how these products in the art and as claimed are different one from the other. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433

(CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972) . In this case, the claimed products and those disclosed in the art are the same. This is further supported by Applicants own method claims which recite and encompass producing a cloned viable animal, which by its very nature should produce the same animal from which the donor cells were obtained. Given the breadth of the claims, to any non-human animal or cells derived from the cloned non-human animal, any non-human animal or cells would anticipate the claims. Examiner acknowledges that the claimed method is not taught in any of the cited references, however Applicants have failed to teach how their instantly claimed animal produced by the disclosed methods would be different from that taught by the cited references.

Therefore, for the reasons above and of record, the rejections are maintained.

.Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48, 50, 60, 62 and 76 stand and newly amended claims 49, 51-59, 61, 64-75, and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cibelli *et al.*, Plump *et al.* and Arbones *et al.*

Applicants review the basis of the rejection and summarize the teaching of each of the references, noting how each reference by itself fails to teach certain limitations. In particular, Applicants argue that ES cells are widely recognized in the art to be suitable for homologous recombination and that there is nothing in Arbones *et al.* to suggest the appropriateness for the use of a myoblast cell as a donor cell. Applicants argue that the teaching of Arbones *et al.* just teaches the art recognized methodology of culturing cells long term in order to confirm a genetic alteration to a cell. See Applicants' amendment, pages 14-16. Applicants' arguments have been fully considered, but not found persuasive.

Applicants final summary of Arbones *et al.* is exactly what is relied upon for the basis of the obvious rejection. Examiner acknowledges that the art recognizes that ES cells appear to maintain an increased ability to undergo homologous recombination, and that other cell types and cell lines require greater manipulation in order to obtain the cell with a desired genetic alteration. Thus, it would be obvious that if the artisan were to use a cell line that require greater cell doublings to confirm a desired genetic alteration such methodology would be used. Nuclear transfer methodology allows for the use of any nuclear material, either from ES cells or somatic cells. The methodology remedies a long time problem that ES cells do not exist for all species of animals, and that somatic cells can be used in generating cloned animals or genetically altered animals of a given species. Clearly the art supports the use of somatic cells for nuclear transfer methodology, and the genetic alteration of these donor cells. Given art recognized limitations for

generating and confirming a genetic alteration of interest in a somatic cell it would be obvious to use the methods and guidance of Arbones *et al.* to affect a given genetic alteration in a somatic cell.

It is noted the claims have been amended, accordingly, claims previously indicated as anticipated are now included in the basis of the instant rejection. The claims have been amended to encompass that the donor cell has been cultured for at least five passages, which is not specifically taught by any one reference. However, as reasoned above, would be obvious to one of ordinary skill in the art depending on the donor cell, in particular for cells that differ in their ability to undergo homologous recombination, like somatic cells.

Conclusion

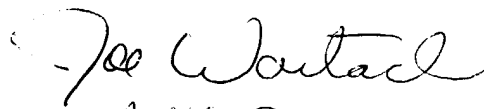
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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